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75269-1CIP5



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that I verily believe that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**METHODS FOR STERILIZING BIOLOGICAL MATERIALS**

the specification of which

- (check one) ☐ is attached hereto.
- ☒ was filed on MARCH 23, 2000
- as U.S. Application Serial No. \_\_\_\_\_
- ☐ was filed on \_\_\_\_\_
- as PCT International Application No. \_\_\_\_\_

and (if applicable) was amended on \_\_\_\_\_

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information known to me which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §§1.56(a) and (b), which state:

- "(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
- (1) prior art cited in search reports of a foreign patent office in a counterpart application,
  - (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
  - (i) Opposing an argument of unpatentability relied on by the Office, or
  - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability."

I hereby claim foreign priority benefits under 35 United States Code, §119 and/or §365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate filed by me or my assignee disclosing the subject matter claimed in this application and having a filing date (1) before that of the application on which priority is claimed, or (2) if no priority claimed, before the filing of this application:

PRIOR FOREIGN APPLICATION(S)

<u>Number</u>	<u>Country</u>	<u>Filing Date</u> <u>(Day/Month/Year)</u>	<u>Date First</u> <u>Laid-open or</u> <u>Published</u>	<u>Date Patented</u> <u>or Granted</u>	<u>Priority Claimed?</u>
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I hereby claim the benefit under 35 United States Code, § 119(e) of any United States provisional application(s) listed below:

<u>Application Number</u>	<u>Filing Date</u>
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I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

PRIOR U.S. OR PCT APPLICATION(S)

<u>Application No.</u>	<u>Filing Date</u> <u>(day/month/year)</u>	<u>Status</u> <u>(pending, abandoned, granted)</u>
08/095,698	22/07/93	granted
PCT/CA94/00401	22/07/94	pending
08/573,149	15/12/95	pending

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the following patent agents with full power of substitution, association and revocation to prosecute this application and/or international application and to transact all business in the Patent and Trademark Office connected therewith:

JAMES D. KOKONIS (Reg. No. 21178)  
ALAN R. CAMPBELL (Reg. No. 26129)  
A. DAVID MORROW (Reg. No. 28816)  
JAMES MCGRAW (Reg. No. 28168)  
JOHN BOCHNOVIC (Reg. No. 29229)  
JOY D. MORROW (Reg. No. 30911)  
TOKUO HIRAMA (Reg. No. 32551)  
YWE J. LOOPER (Reg. No. 43758)  
KOHJI SUZUKI (Reg. No. 44467)  
R. JOHN HALEY (Reg. No. 29502)  
JAMES A. OLIFF (Reg. No. 27075)  
KIRK M. HUDSON (Reg. No. 27562)  
EDWARD P. WALKER (Reg. No. 31450)

HUGH O'GORMAN (Reg. No. 26140)  
NICHOLAS H. FYFE (Reg. No. 26134)  
ROBERT D. GOULD (Reg. No. 27523)  
THOMAS R. KELLY (Reg. No. 29244)  
MICHAEL E. WHEELER (Reg. No. 29246)  
DONALD F. PHENIX (Reg. No. 32528)  
R. ALLAN BRETT (Reg. No. 40476)  
PHILIP D. LAPIN (Reg. No. 44443)  
GRANT W. LYNDIS (Reg. No. 44484)  
CHRISTINE N. GENGE (Reg. No. P-45405)  
WILLIAM P. BERRIDGE (Reg. No. 30024)  
THOMAS J. PARDINI (Reg. No. 30411)

PLEASE SEND CORRESPONDENCE TO:

OLIFF & BERRIDGE  
277 South Washington Street  
Suite 500  
Washington, D.C. 22314  
U.S.A.  
Telephone: (703) 836-6400  
Facsimile: (703) 836-2787

1) INVENTOR'S SIGNATURE: Randall S. Kent Date: August 14, 2000

Inventor's Name: Randall S. Kent  
(First) (Middle) (Family Name)

Country of Citizenship: U.S.A.

Residence: Thousand Oaks, California, U.S.A.  
(City, State, Country)

Post Office Address: 3512 Radcliffe, Thousand Oaks, California 91360, U.S.A.

2) INVENTOR'S SIGNATURE: Edward A. Horton Date: OCTOBER 9/00

Inventor's Name: Edward A. Horton  
(First) (Middle) (Family Name)

Country of Citizenship: Canada

Residence: Toronto, Ontario, Canada  
(City, Province, Country)

Post Office Address: 100 Lawton Boulevard, Toronto, Ontario, M4V 2A3, Canada

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 CFR 1.9(f) AND 1.27 (c)) - SMALL BUSINESS CONCERN**

Docket No.

Serial No.

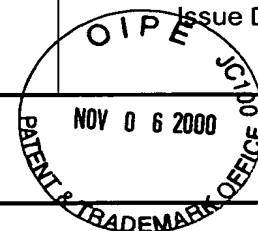
09/533,347

Filing Date

March 23, 2000

Patent No.

Issue Date

 Applicant/ **RANDALL S. KENT, ET AL**  
 Patentee:
Invention: **METHODS FOR STERILIZING PRODUCTS**

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:  
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: **CLEARANT, INC.**ADDRESS OF CONCERN: **11111 Santa Monica Boulevard, Suite 650, Los Angeles, California 90025, U.S.A.**

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above identified invention described in:

- ☐ the specification filed herewith with title as listed above.  
☒ the application identified above.  
☐ the patent identified above.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern or organization exists.  
☐ each such person, concern or organization is listed below.

FULL NAME

ADDRESS

☐

Individual

☐

Small Business Concern

☐

Nonprofit Organization

FULL NAME

ADDRESS

☐

Individual

☐

Small Business Concern

☐

Nonprofit Organization

FULL NAME

ADDRESS

☐

Individual

☐

Small Business Concern

☐

Nonprofit Organization

FULL NAME

ADDRESS

☐

Individual

☐

Small Business Concern

☐

Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING:

Richard A. Anderson

TITLE OF PERSON SIGNING

OTHER THAN OWNER:

Chief Financial Officer

ADDRESS OF PERSON SIGNING:

11111 Santa Monica Blvd.  
 Suite 650  
 Los Angeles, CA 90025

SIGNATURE:

Richard A. Anderson

DATE:

9/29/00